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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,667	10/15/2001	Donald J. McMichael	17350	3464
23556	7590	09/08/2003	EXAMINER	
KIMBERLY-CLARK WORLDWIDE, INC. 401 NORTH LAKE STREET NEENAH, WI 54956			GITOMER, RALPH J	
		ART UNIT	PAPER NUMBER	
		1651	14	
DATE MAILED: 09/08/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/977,667	MCMICHAEL ET AL.	
	<b>Examiner</b> Ralph Gitomer	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 04 June 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) 17-50 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-16 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6) Other:

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Applicant's election with traverse of Group 1, claims 1-16, in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the claims of Group II have not been classified. This is not found persuasive because classification is not a criterion of restriction and the claims as presented are not classifiable by the examiner because they are directed to a system.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(a) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Jackson in view of each of Orsonneau and Boguslaski.

Jackson (US 5,593,851) entitled "Test Kit for the Rapid Detecting of Helicobacter pylori in Gastric Biopsy Tissue" teaches in column 2 second paragraph, a test kit with a first substrate containing urea, and a separate substrate containing pH dye for testing biopsy specimens. In column 3 lines 36-44, a means for handling a biopsy specimen is mounted in the kit having two arms. In column 3 lines 27-35, the kit contains a well with a single test composition containing urea and a dye indicator.

The claims differ from Jackson in that they recite the specimen is first contacted with urea, and then contacted with an indicator where the two components are separate.

Orsonneau (FR 2654436) entitled "Measurement of Urea or Urease In Biological Fluids" teaches in the abstract, determining fluids by contacting with a pH dye, a number of which are listed on page 5 first paragraph, then contacting with urea and detecting a color change.

Boguslaski (5,420,016) entitled "Test Device and Kit for Detecting Helicobacter pylori" teaches in the abstract, a test strip with two components, one containing a urease substrate and the other containing a pH indicator. Phenol Red is shown in column 6. In column 3, lines 12-22, isolation of the substrate reaction to produce ammonia from an optimized test indicator reaction to detect generated ammonia is

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shown. By doing this, the sample components do not interfere with the indicator and the sample can be incubated at a pH that is optimal for urease and the buffer does not have an adverse effect on sensitivity.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the dual components of each or Orsonneau and Boguslaski in the method of Jackson because the secondary references teach separating the urea and indicator where Jackson teaches all the features of the present invention but with the two reagents in a single composition. To separate reagents would have the expected results as taught by Boguslaski of permitting optimized compositions and increased sensitivity.

Regarding the dependent claims directed to the form of the urea, various dry reagents are taught in the above references. And the gel and agar of claims 5 and 6 are also taught by the above references.

Claims 1-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 line 5, "being capable of" is improper because compounds do not have capabilities.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

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The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Roda (Anal Biochem) teaches detecting HP.

BR 8902699 A, abstract only available, teaches a single composition for detecting HP.

Klein (EP 369292) teaches detecting HP with a single composition.

Jackson (5,668,011) teaches a fork for handling biopsy specimens.

Jackson (5,439,801) teaches detecting HP.

Lee (6,187,556) teaches detecting HP.

Boguslaski (5,314,804) teaches a test for HP.

Heckenmuller (5,679,570) teaches detecting HP.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing

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applications electronically, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.



Ralph Gitomer  
Primary Examiner  
Group 1651

RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200